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EXAMINER

COLLINS, CYNTHIA E

ART UNIT PAPER NUMBER

DATE MAILED 05/12/2003

Please find below and or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/846,903

Applicant(s)

CONNER ET AL.

Examiner

Cynthia Collins

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 12 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 24-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____

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DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-23 and SEQ ID NO:79, in Paper No. 7 is acknowledged. The traversal is on the ground(s) that a search and examination of Groups I and II would not be unduly burdensome. This is not found persuasive because while the searches of Groups I and II may overlap, their searches are not coextensive of each other. In this particular instance, a search of Group II is not coextensive with a search of Group I, since Group II requires a search for methods not claimed in Group I. Accordingly, claims 24-27 and the nonelected sequences are withdrawn from consideration as being directed to nonelected inventions.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449 is attached to the instant Office action.

Claim Objections

Claims 1, 10, 14-18 and 22-23 are objected to because they recite nonelected sequences. Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an isolated nucleic acid comprising a sequence of SEQ ID NO:79, or any fragment, region or *cis* element thereof, capable of regulating transcription of an operably linked DNA sequence, as well as a cell comprising said sequence, and methods of using said sequence.

In contrast, the specification describes only an isolated nucleic acid obtained from maize comprising nucleotides 417 to 2213 of SEQ ID NO:79 (designated SEQ ID NO:94) that functions as a promoter in a wheat anther transient assay (Table 2 page 70, page 71 lines 16-23), and in transgenic *Arabidopsis* plants (Table 3 page 78, page 79 lines 10-17). The specification does not characterize SEQ ID NO:79 as having promoter function. The specification does not describe or characterize any fragment, region or *cis* element of SEQ ID NO:79, other than SEQ ID NO:94, as having or affecting promoter function.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise

definition, such as its structure (formula for chemical name) of the claimed subject matter

F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that

"to posit a type of material generally known to exist in the presence of knowledge as to what that

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material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus as broadly claimed. Given the lack of written description of the claimed products, any method of using them would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing. See Written Description Requirement guidelines published in Federal Register/ Vol. 66, No.4/ Friday January 5, 2001/Notices: pp. 1099-1111).

Claims 1-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid comprising a sequence of SEQ ID NO:94 capable of regulating transcription of an operably linked DNA sequence, including transcription in anthers, does not reasonably provide enablement for an isolated nucleic acid comprising a sequence of SEQ ID NO:79 or any fragment, region or *cis* element thereof, capable of regulating transcription of an operably linked DNA sequence in any male reproductive tissues, or for said isolated nucleic acid further comprising a minimal promoter. The specification does not enable one to make and use the invention which it is intended to describe, or with which it is most nearly connected, to

The claims are drawn to an isolated nucleic acid, including a promoter and a hybrid promoter, comprising a sequence of SEQ ID NO:79 or any fragment, region or *cis* element

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thereof, capable of regulating transcription of an operably linked DNA sequence, including transcription in male reproductive tissues, anthers and wheat anthers, as well as a cell comprising said sequence, and methods of using said sequence. The claims are also drawn to said isolated nucleic acid further comprising a minimal promoter, including a minimal CaMV promoter and a rice actin promoter. Claims 18 and 22 are drawn to ligating an entire promoter of SEQ ID NO:79 to a second promoter or to a minimal promoter respectively.

The specification discloses an isolated nucleic acid obtained from maize comprising nucleotides 417 to 2213 of SEQ ID NO:79 (designated SEQ ID NO:94) that functions as a promoter in a wheat anther transient assay (Table 2 page 70, page 71 lines 16-23). The specification also discloses that the isolated nucleic acid comprising nucleotides 417 to 2213 of SEQ ID NO:79 (designated SEQ ID NO:94) exhibits promoter function in transgenic *Arabidopsis* plants in anthers, immature seed, seedlings and cut stems, but not in leaves, roots, or other floral organs (Table 3 page 78, page 79 lines 10-17). The specification does not disclose whether SEQ ID NO:79 or any other fragment or region thereof exhibits promoter function. The specification does not disclose the structure and function of any *cis* element of SEQ ID NO:79. The specification does not disclose promoter function in any tissue other than in anthers, immature seed, seedlings and cut stems. The specification does not disclose SEQ ID NO:79 or any fragment, region or *cis* element thereof as having promoter function when further comprising a minimal promoter.

Claim 18 is drawn to a nucleic acid comprising the isolated nucleic acid as described above, but does not

unpredictable. Sequences that are contiguous subfragments of a DNA sequence cannot predictably be assumed to have general or specific promoter activity. This unpredictability

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originates in the mechanics of promoter function, which requires the presence of particular nucleotides in the sequence to mediate a general or specific promoter function. As a consequence, it is unpredictable whether any sequence which is a part of a known tissue-specific promoter would retain general promoter function or tissue-specific function, because it is unpredictable whether a sequence which is a part of a known tissue-specific promoter would retain all the particular nucleotides necessary to mediate general or specific promoter function. Guidance is also necessary because the ability of a promoter fragment to generally or specifically enhance the expression of an operably linked minimal promoter is also unpredictable. A promoter region that generally or specifically enhances the expression of a native promoter may or may not enhance the expression of an operably linked minimal promoter.

For Example, Hamilton et al. (Plant Molecular Biology, 1998, Vol. 38, pages 663-669, Applicant's IDS) teach that nucleotides -84 to -53 of the maize ZM13 promoter are required for pollen-specific promoter function (page 665 Figure 1). Hamilton et al. also teach that a six base pair general enhancer element enhances the expression of the native ZM13 promoter, but does not enhance the expression of an operably linked minimal CaMV 35S promoter (page 665 Figure 1). Similarly, Tsuchiya et al. (Plant Molecular Biology, 1994, Vol. 26, pages 1737-1746, Applicant's IDS) teach that nucleotides -1273 to -1095 of the rice Osg6B promoter are required for tapetum-specific promoter function, and that nucleotides -1095 to 0 are required for general promoter function (page 1743 Figure 5).

DNA sequences to use as a promoter, or as a tissue-specific promoter. It would also require

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undue experimentation to obtain promoter function following the ligation of an entire promoter comprising SEQ ID NO:79 to an additional minimal promoter or to a second entire promoter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-8, 11-13, 17-18 and 22, and claims dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3 and 17 are indefinite in the recitation of "hybrid". It is unclear what the promoter is a hybrid of.

Claims 4-6, 11-13 and 18 are indefinite in the recitation of "enhanced", as "enhanced" is a relative term lacking a comparative basis.

Claims 7, 8 and 22 are indefinite in the recitation of "minimal", as it is unclear what aspects(s) of the promoter have been minimized.

Claim 18 is indefinite in the recitation of "method of claim 16 wherein operably linking the nucleic acid sequence selected from the group consisting of SEQ ID NOS:79-98 or fragment thereof to the promoter confers expression of operably linked genes in male reproductive tissues". Since claim 16 does not recite fragments of the SEQ ID NOs, "or fragment thereof" lacks antecedent basis. Furthermore, since "gene" is recognized in the art to comprise a promoter SEQ ID NO: 9 to another promoter, which is in turn ligated to a coding sequence, which is confusing.

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The following amendments would obviate this rejection:

In claim 16, line 3, insert --or a fragment thereof-- before the period (note that this would not address the rejections under 35 USC 112, first paragraph).

In claim 18, line 3, replace "operably linked genes" with --an operably linked transcribable DNA sequence--.

Claim 22 is indefinite in its recitation of "the method of claim 16 ... SEQ ID NOS: 79-98 or fragment ...". Since claim 16 is only drawn to the entire SEQ ID NO:79, "fragment, region or cis element" lacks antecedent basis and fails to further limit the claim.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 10-13 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 10-13, as written, do not sufficiently distinguish over nucleic acids as they exist naturally because the claims do not particularly point out any non-naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See Diamond v. Chakrabarty, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 10-15, 18-21 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Terada et al. (Plant Molecular Biology, 1995, Vol. 27, pages 17-26).

The claims are drawn to an isolated nucleic acid, including a promoter comprising a sequence of SEQ ID NO:79, or any fragment, region or *cis* element thereof, capable of regulating transcription of an operably linked DNA sequence, including transcription in male reproductive tissues, anthers and wheat anthers, as well as a cell comprising said sequence, and methods of using said sequence.

Terada et al. teach an isolated wheat histone H3 promoter capable of regulating transcription of an operably linked gusA DNA sequence, including transcription in anthers of transgenic plants, as well as a cell comprising said sequence, and methods of using said sequence (page 22 Figure 3, page 23 column 1). While Terada et al. do not teach a promoter comprising the entire sequence of SEQ ID NO:79, the promoter taught by Terada et al. comprises a fragment or region or *cis* thereof, as the claim places no limitations on the size of the fragment or region. Furthermore, while Terada et al. do not explicitly teach the regulation of transcription in wheat anthers, such a function would be inherent in the promoter taught by Terada et al. as the

Claims 1-15 and 18-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Zabaleta et al. (The Plant Journal, 1998, Vol. 15, No. 49-59).

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The claims are drawn to an isolated nucleic acid, including a promoter and a hybrid promoter, comprising a sequence of SEQ ID NO:79, or any fragment, region or *cis* element thereof, capable of regulating transcription of an operably linked DNA sequence, including transcription in male reproductive tissues, and anthers, as well as a cell and plants comprising said sequence, and methods of using said sequence. The claims are also drawn to said isolated nucleic acid further comprising a minimal promoter, including a minimal CaMV promoter.

Zabaleta et al. teach a hybrid promoter comprising an isolated nuclear-encoded respiratory chain Complex I gene promoter further comprising a minimal CaMV promoter, said hybrid promoter being capable of regulating transcription of an operably linked *gusA* DNA sequence, including transcription in anthers of transgenic plants, as well as a cell comprising said sequence, and methods of using said sequence (page 56 Figure 5). While Zabaleta et al. do not teach a promoter comprising the entire sequence of SEQ ID NO:79, the promoter taught by Zabaleta et al. comprises a fragment or region or *cis* thereof, as the claim places no limitations on the size of the fragment or region. The ability to function in wheat anthers would have been inherent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in

Claims 3-9 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terada et al. (Plant Molecular Biology, 1995, Vol. 27, pages 17-26) in view of Zabaleta et al. (The Plant Journal, 1998, Vol. 15, No. 49-59).

The claims are drawn to an isolated nucleic acid comprising a hybrid promoter comprising a sequence of SEQ ID NO:79, or any fragment, region or *cis* element thereof, said hybrid promoter being capable of regulating transcription of an operably linked DNA sequence in wheat anthers.

The teachings of Terada et al. are discussed *supra*.

Terada et al. do not teach a hybrid promoter.

The teachings of Zabaleta et al. are discussed *supra*.

Given the success of Terada et al. in making an isolated wheat histone H3 promoter capable of regulating transcription of an operably linked DNA sequence in wheat anthers, and give the success of Zabaleta et al. in making a hybrid promoter comprising an isolated nuclear-encoded respiratory chain Complex I gene promoter further comprising a minimal CaMV promoter, said hybrid promoter being capable of regulating transcription of an operably linked DNA sequence in anthers, it would have been *prima facie* obvious to one skilled in the art at the time the invention was made to combine the isolated wheat histone H3 promoter taught by Terada et al. with a minimal CaMV promoter as taught by Zabaleta et al. to make a hybrid promoter, given the express purpose of regulating transcription of an operably linked DNA sequence in wheat anthers, without any surprising or unexpected results. Accordingly, one of ordinary skill in the art would have had a reasonable expectation of success. Thus, the claimed invention would have been *prima facie* obvious as a *substantially obvious* combination of the teachings of Terada et al. and Zabaleta et al. at the time the invention was made.

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Remarks

No claim is allowed.

Claims 16-17 are deemed free of the prior art of record, given the failure of the prior art to teach or suggest a method of regulating transcription using a promoter of SEQ ID NO:79.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210.

The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC

March 7, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

David T. Fox